REMARKS

The Applicants wish to thank the Examiner for his review of the present application. Applicants have amended claims 69 and 80 to address the claim rejections based on 35 U.S.C. §112. Applicants have also amended claims 78, 79, 88, and 89. Claims 69-72, 75-89 are currently pending in the application. No new matter has been added.

35 U.S.C. §112

The Office Action rejects claims 69-72 and 75-89 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In particular, the Office Action indicates that claims 69 and 80 begin with the preamble "A method of treating…", yet the claimed invention is directed to diagnosis. Applicants have amended claims 69 and 80 such that the preambles now read "A method of diagnosing…." Accordingly, Applicants now believe that this rejection is now moot.

35 U.S.C. §102(b)

The office action rejects claims 69, 70, 75-81, and 84-89 under 35 U.S.C. §102(b) as being unpatentable over Delp et al. (U.S. patent no. 5,682,886), hereinafter referred to as "Delp."

Amended claim 69 defines, in relevant part, a method of diagnosing a human with joint disease including obtaining an electronic image of a joint, electronically evaluating the image to obtain information, and determining biomechanical data associated with the joint. Determining biomechanical data includes determining at least one axis associated with the joint. The at least one axis is associated with a femoral condyle coordinate system and includes one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. The method then shapes a physical model based, at least in part, upon the obtained information and the biomechanical data.

Delp fails to teach such a method. Rather, Delp discloses a method for planning surgery on a body portion. In particular, Delp obtains image data of the patient's leg and then generates a three-dimensional computer model of the bones (col. 8, lines 32-65). After some additional processing (e.g., identifying joint centers, creating surface patches, etc.), Delp uses the data to determine the femoral mechanical axis and the tibial mechanical axis, which are, in turn, used to

determine the proper limb alignment in order to plan a surgery. Nowhere does Delp teach or suggest anything relating to the shaping of a *physical* model, as required by amended claim 69. Rather, as mentioned above, at best, Delp utilizes *computer* models (which are not physical models) created from the obtained image data.

Moreover, nowhere does Delp teach or suggest shaping a *physical* model based, at least in part, upon the information obtained from electronically evaluating the image, and the biomechanical data associated with the joint. Rather, Delp uses the computer model to determine the femoral and tibial axes. This is in direct contrast to amended claim 69, which describes a method that shapes a physical model based upon biomechanical data (e.g., at least one axis associated with the joint and a femoral condyle coordinate system). In other words, amended claim 69 uses the biomechanical data to shape the physical model, whereas Delp uses the computer model to determine the biomechanical data (e.g., joint center data, and the femoral and tibial axes).

The Office Action suggests that Delp teaches using the obtained information to shape an implant (e.g., at Col. 12, line 63 through Col. 14, line 63). Applicants respectfully disagree. Even if the implant could constitute the physical model, rather than teaching or suggesting shaping an implant using the obtained information, the passage relied upon by the Office Action states that Delp is merely able to select an appropriate implant (e.g., the size and pose) from a set of pre-identified implants. Nowhere does Delp teach or suggest shaping a physical model based, at least in part, upon the information and biomechanical data – Delp merely selects an implant from a list of pre-set implant sizes, which must be loaded into the system. Amended claim 69 is therefore allowable over Delp. Moreover, claims 70 and 75-79, which depend from claim 69, are allowable for at least the same reasons.

In a manner similar to amended claim 69, amended claim 80 also defines a method that determines biomechanical data that includes at least one axis (one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis) associated with the joint and uses the information and biomechanical data to shape a physical model. However, unlike claim 69, the axis described in claim 80 is associated with a tibial condyle coordinate system (e.g., rather than a femoral condyle system). Like the femoral condyle coordinate system, the tibial condyle

coordinate system is also defined by the medial-lateral axis, inferior-superior axis, and the anterior-posterior axis. Accordingly, amended claim 80 is allowable over Delp for at least the same reasons as discussed above with regard to amended claim 69. Moreover, claims 81 and 84-89, which depend from claim 80, are allowable for at least the same reasons.

35 U.S.C. §103(a)

The office action rejects claims 69, 70, 71, 76, 80, 81, 82, and 86 under 35 U.S.C. 103(a) as being unpatentable over Kshirsagar et al. (Investigative Radiology, vol. 33, no. 5; hereinafter "Kshirsagar") in view of Delp

As discussed above, amended claims 69 and 80 define, in relevant part, methods of diagnosing a human with joint disease including obtaining an electronic image of a joint, electronically evaluating the image to obtain information, and determining biomechanical data associated with the joint. Determining biomechanical data includes determining at least one axis associated with the joint. The at least one axis is associated with a femoral condyle coordinate system (or tibial coordinate system for claim 80) and includes one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. The method then shapes a physical model based, at least in part, upon the information and biomechanical data.

Kshirsagar fails to teach such methods. Rather, Kshirsagar teaches a method of measuring localized cartilage volume and thickness of human knee joints by analyzing three-dimensional MRIs. As indicated in the office action, Kshirsagar fails to teach or suggest determining an axis (i.e., one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis) associated with the joint and a femoral condyle coordinate system. Additionally, nowhere does Kshirsagar teach or suggest using the information obtained from the image and the biomechanical data to shape a physical model.

The office action adds Delp to teach the missing elements, namely, determining an axis associated with a femoral condyle coordinate system and including one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. However, as discussed above, Delp fails to teach or suggest using the information obtained from the image and the biomechanical data to shape a physical model. Rather, Delp uses a 3D *computer* model to determine the femoral and

tibial mechanical axes and plan a surgery. Accordingly, because neither Kshirsagar nor Delp teach or suggest, alone or in combination, all limitations of amended claims 69 and 80, the combination cannot make the claims obvious. Additionally, claims 70, 71, 76, 81, 82, and 86, which depend from claims 69 and 80, are allowable for at least the same reasons.

The office action rejects claims 77, 78, 87, and 88 under 35 U.S.C. 103(a) as being unpatentable over Kshirsagar, in view of Delp, and further in view of U.S. Patent Number 6,203,546 (MacMahon, hereinafter "MacMahon").

As dependent claims of claims 69 and 80, claims 77, 78, 87, and 88 also define methods that determine biomechanical data, including an axis (one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis) associated with either a femoral or tibial condyle coordinate system, and use information obtained from an image and the biomechanical data to shape a physical model.

As discussed above, neither Kshirsagar nor Delp, teach or suggest, alone or in combination, using the information and biomechanical data to shape a physical model, as required by claims 77, 78, 87, and 88. Accordingly, claims 77, 78, 87, and 88 are allowable over the combination of Kshirsagar and Delp.

Additionally, MacMahon fails to teach the deficiencies of Kshirsagar and Delp. In particular, MacMahon also fails to teach or suggest using information and biomechanical data (including the axes described above) to shape a physical model. Rather, MacMahon teaches a method and apparatus for medial tibial osteotomy. In particular, MacMahon utilizes the mechanical axes of the femur and tibia to determine the lateral thrust produced by the subject's body weight during walking. MacMahon then uses a computer simulation and the value of the lateral thrust to determine the correct position of the knee (i.e., where lateral thrust is zero). Accordingly, because MacMahon does not teach or suggest, alone or in combination with Kshirsagar and Delp, all of the limitations of claims 77, 78, 87, and 88, the combination cannot make the claims obvious.

The office action rejects claim 72 and 83 under 35 U.S.C. 103(a) as being unpatentable over Kshirsagar in view of Delp.

As dependent claims of claims 69 and 80, claims 72 and 83 also define methods that

shape a physical model based at least in part upon information obtained from an image and biomechanical data associated with a joint. As discussed above, neither Kshirsagar nor Delp, teach or suggest, alone or in combination, shaping a physical model, as required by claims 72 and 83. Accordingly, claims 72 and 83 are allowable over the combination of Kshirsagar and Delp.

The office action rejects claim 69, 70, 76, 80, 81, and 86 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 6,560,476 (Pelletier et al., hereinafter "Pelletier") in view of Delp.

As mentioned above, claims 69 and 80 describe, in relevant part, methods of diagnosing a human with joint disease including obtaining an electronic image of a joint, electronically evaluating the image, and determining biomechanical data associated with the joint. Determining biomechanical data includes determining at least one axis associated with the joint. The at least one axis is associated with a femoral condyle coordinate system (or tibial coordinate system for claim 80) and includes one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. The method then shapes a physical model based, at least in part, upon the information and biomechanical data.

Pelletier fails to teach such a method. Rather, Pelletier discloses an orthopedic magnetic resonance imaging system for evaluating disease progression. As suggested in the office action, Pelletier fails to teach or suggest that the biomechanical data includes at least one axis associated with the joint and a femoral condyle coordinate system (claim 69) or tibial condyle coordinate system (claim 80). Additionally, Pelletier also fails to teach or suggest that the at least one axis includes one of a medial-lateral axis, an inferior-superior axis, and an anterior-posterior axis. Furthermore, Pelletier fails to teach or suggest using information and biomechanical data obtained/determined from the image to shape a physical model.

As described above, Delp also fails to teach or suggest using information and biomechanical data to shape a physical model. Accordingly, because neither Pelletier nor Delp teach or suggest, alone or in combination, all limitations of amended claims 69 and 80, the combination cannot make the claims obvious. Additionally, claims 70, 76, 81, and 86, which depend from claims 69 and 80, are allowable for at least the same reasons.

It is believed that the application is now in order for allowance and Applicants

respectfully request that a notice of allowance be issued. Applicants believe that a three month extension of time is required and request that the associated fee be charge to deposit account number 19-4972. Applicants also request that any additional fees required by this paper be charged to or any overpayments be credited to deposit account number 19-4972. Applicants also request that the examiner contact applicant's attorney, Jonathan Lovely, if it will assist in processing this application through issuance.

Respectfully Submitted,

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